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(71) Applicant *(for all designated States except US)*: **CITRON LIMITED** [—/—]; Road Town, Tortola (VG).

(72) Inventor; and

(75) Inventor/Applicant *(for US only)*: **DiMACCIO, John, P.** [US/US]; 2747 Llama Court, Carlsbad, CA 92009 (US).

(74) Agents: **WONG, James, J.** et al.; Campbell & Flores LLP, 7th Floor, 4370 La Jolla Village Drive, San Diego, CA 92122 (US).

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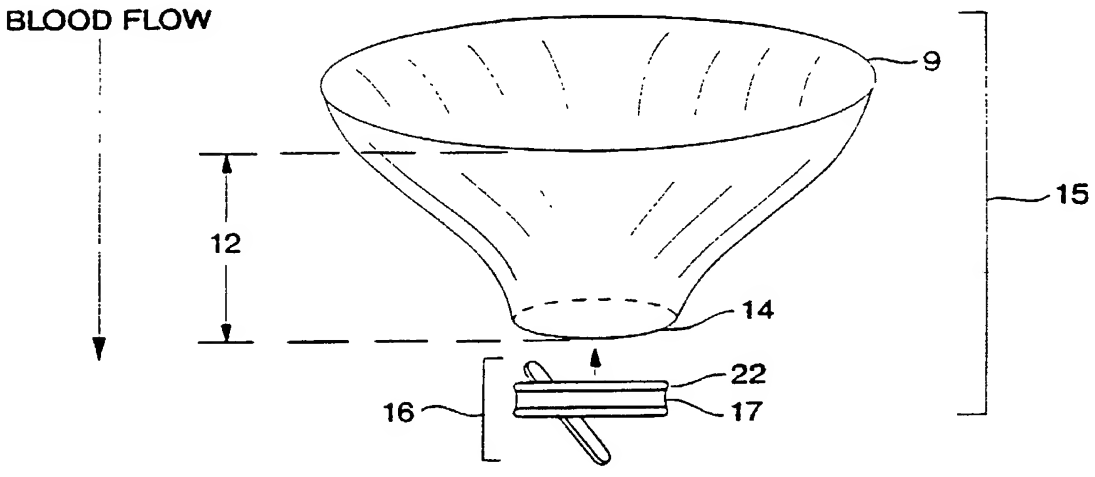
(54) Title: AUTOLOGOUS TISSUE SUTURE RING USED IN HEART VALVE IMPLANTATION



(57) Abstract: A tissue suture ring manufactured from autologous tissue useful for affixing a replacement heart valve prosthesis to the operational location of the valve in the recipient's heart, the combination of the tissue suture ring and a replacement heart valve prosthesis, methods of manufacturing said tissue suture ring, and methods of using the tissue suture ring.

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AUTOLOGOUS TISSUE SUTURE RING USED IN HEART VALVE IMPLANTATION

FIELD OF INVENTION

This invention relates to devices and articles of manufacture used affixing implantable mechanical and bioprosthetic devices, such as heart valves, which are used to replace natural portions of the various body organs.

BACKGROUND OF THE INVENTION

The human heart is the primary organ that moves blood through the body. It circulates blood to and from the lungs for oxygenation, and then to all points of the rest of body and back. Blood is moved by the precisely timed contractions of the four chambers of the heart, right atrium, right ventricle, left atrium and left ventricle. The very critical function of regulating the flow of blood through the various chambers of the heart is carried out by the four heart valves, pulmonary, tricuspid, aortic and mitral. With advancing age, heart valves can begin to fail due to damage from disease or infections. Faulty heart valves can also be the result of congenital conditions. Some heart valve conditions can be treated with medication. However, very often the only recourse for the patient is surgical replacement of the faulty valve.

Replacement heart valve surgery has become commonplace, however, it is still nonetheless a complicated and risky operation. The procedure requires the patient being placed on a heart lung machine, which oxygenates and circulates the patients blood the surgeon

performs the open heart procedure. The surgeon upon entering the heart, evaluates the condition of the existing valve, and if necessary, removes the valve and replaces it with a prosthetic valve.

There are two types of prosthetic valves in use, mechanical and bioprosthetic. A standard implantable mechanical heart valve typically has an annular valve housing or body to provide a passageway for blood. Occluders are mounted in the annular body and open or close the blood flow passageway. There can be one or more occluders. On the outside of the valve body there is usually an external, circumferential surface typically configured as a groove to facilitate attachment of a suture ring to the valve body. The function of the suture ring is to affix the mechanical valve to the heart tissue.

A standard bioprosthetic heart valve bears a close resemblance to the human valve it is replacing. The valve leaflets of the bioprosthetic valve are usually fashioned from chemically treated animal tissue, such as the heart valves from a pig heart that have been fixed in glutaraldehyde or similar fixatives. The valve mechanism of the bioprosthetic valve function in an identical fashion as the natural valves. Similar to the mechanical valve, the bioprosthetic valve has around its circular base a suture ring used for affixing the valve to heart tissue.

The suture ring is used to sew the heart valve to the patient's heart tissue. The ring generally comprises a knit fabric tube which is rolled into a toroidal form and which is secured about the heart valve in the circumferential groove. Various methods and

apparatus have been proposed for securing the suture ring to the heart valve. It is known, for instance, to bind the ring into the groove with a plastic thread. It has also been proposed to form a rotatable suture on the heart valve using heat shrinkable plastic material, as disclosed in U.S. Pat. No. 3,781,969. U.S. Pat. No. 3,491,376 suggest that a suture ring should be formed as a separate sub-assembly which should then be attached to the heart valve. In the '376 patent, the suture ring is described as including a resilient annular member which is temporarily deformed, so as to snap onto the valve body. U.S. Pat. No. 3,579,642 proposes the use of metal snap rings which must be radially expanded to place the suture ring about the valve body. U.S. Patent No. 4,743,253 proposed a two-part suture ring comprising the knit fabric and an internal crescent-shaped ring which would be deformed inwardly by electromagnetic forming to clamp the heart valve while permitting relative rotation between the suture ring and the heart valve.

Despite these efforts to improve the functionality of the suture ring, there remains unaddressed issues relating to suture rings. For example, suture rings are made from synthetic materials that can and often lead to thrombus, pannus and fibrosis in the replacement valve. This condition can hinder the functioning of the replacement valve, and over time may require replacement of the replacement valve. Suture rings are relatively bulky for the space where they are placed. Their bulk reduces the space available for the heart valve assembly, making it difficult if not impossible to orthotopically place the valve in its most ideal location. The additional bulk also increases the time required for the procedure. Additionally , if the patient develops a septic infection, the bacteria

associated with such infections often attach to the synthetic material of the suture rings. Once the bacteria contaminates the suture ring, the infection is extremely difficult to eradicate. Failure to control the infection could ultimately necessitate the surgical replacement of the prosthetic valve. In instances where the patient is a child or small adult, the space taken by the suture ring forces the surgeon to work in less space and sometime resulting in the implantation of a smaller than ideal sized prosthetic valve. Any one or combination of the above-mentioned complications could result in the prosthetic heart valve recipient having to undergo a second procedure to remedy the condition. A second procedure means additional risks for the recipient, and potentially substantial costs to the health care provider or insurer, including replacement of the implanted heart valve. Hence, it is of considerable benefit to the recipient, as well as, the health care provider and insurer, to minimize the need to undergo these second procedures.

Surprisingly, a new invention has been made developed which addresses these issues and others, and provides much needed advantages over the existing technology.

SUMMARY OF THE INVENTION

A tissue suture ring manufactured from autologous tissue useful for affixing a replacement heart valve prosthesis to the operational location of the valve in the recipient's heart, the combination of the tissue suture ring and a replacement heart valve prosthesis, methods of manufacturing said tissue suture ring, and methods of using the tissue suture ring.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig 1A is a cross-sectional view showing the tissue suture ring in combination with a mechanical heart valve prostheses in accordance with one embodiment of the current invention. The figure depicts how the tissue suture ring is affixed to the mechanical heart valve prosthesis.

Fig 1B is a cross-sectional view showing the first step of one method for affixing the tissue suture ring to a mechanical heart valve prostheses.

Fig 1C is a cross-sectional view showing the second step of the method of Fig 1B for affixing the tissue suture ring to a mechanical heart valve prosthesis.

Fig 1D is a cross-sectional view showing a second method of affixing a tissue suture ring to the suture ring of a mechanical prosthetic heart valve.

Fig 1E is a cross-sectional view showing a method of affixing a tissue suture ring to the suture ring of a bioprosthetic heart valve.

Fig 2 is a top view of the tissue suture ring as affixed to a mechanical heart valve prosthesis.

Fig 3 is a top view of the tissue suture ring as affixed to a bioprosthetic heart valve prosthesis.

Fig 4 is a cross-sectional perspective view showing the tissue suture ring as affixed to a bioprosthetic heart valve prosthesis.

Fig 5 is a cross-sectional perspective view showing the placement of the first and second excisions used obtaining the pericardial sac tissue used for making the tissue suture ring.

Fig 6 is a cross-sectional perspective view showing the positioning of the tissue suture ring onto a mechanical heart valve prosthesis.

Fig 7 is the top view of a bioprosthetic valve depicting the various parts of the valve.

Fig 8 is a cross-sectional perspective view showing the positioning of the tissue suture ring onto a bioprosthetic heart valve prosthesis.

Fig 9A is a top view showing the first and second conical cross-sections of a completed tissue suture ring.

Fig 9B is a cross-section view of a completed tissue suture ring.

Fig 9C is a cross-section perspective view of a complete tissue suture ring.

DETAILED DESCRIPTION OF THE INVENTION

The present invention is directed to a tissue suture ring manufactured from autologous tissue for affixing a heart valve prosthesis to the heart tissue. An embodiment of the present invention is a tissue suture ring which comprises a conical shell shaped band of tissue with a first edge conical cross section which affixes to a heart valve prosthesis, and a second edge

conical cross section which affixes to a heart valve annulus. A preferred variation of the present embodiment is where the tissue is pericardial tissue. Another preferred variation of the present embodiment is where the heart valve prosthesis is a mechanical heart valve prosthesis, particularly preferred is where the mechanical heart valve is single leaflet disk valve or a bileaflet disk valve. Yet another preferred variation of the present embodiment is where the heart valve prosthesis is a bioprosthetic heart valve.

Another embodiment of the present invention is a heart valve prosthesis comprising, a base having an annular outside portion and a passage allowing the flow of blood through the base, a valve means selectively movable relative to said base to open and close the passage to control the flow of blood through the passage, and a tissue suture ring which comprises a conical shell shaped band of tissue with a first edge conical cross section which affixes to a heart valve prosthesis, and a second edge conical cross section which affixes to a heart valve annulus. A preferred variation of the present embodiment is where the tissue is pericardial tissue. Another preferred variation of the present embodiment is where the heart valve prosthesis is a mechanical heart valve prosthesis, particularly preferred is where the mechanical heart valve is a single leaflet disk valve or a bileaflet disk valve. Yet another preferred variation of the present embodiment is where the heart valve prosthesis is a bioprosthetic heart valve.

Yet another embodiment of the present invention is an improved heart valve prosthesis including, a base having an annular outside portion and a passage allowing

the flow of blood through the base, a valve means selectively movable relative to said base to open and close the passage to control the flow of blood through the passage, in combination with a tissue suture ring which comprises, a conical shell shaped band of tissue with a first edge conical cross section which affixes to a heart valve prosthesis, and a second edge conical cross section which affixes to a heart valve annulus. A preferred variation of the present embodiment is where the tissue is pericardial tissue. Another preferred variation of the present embodiment is where the heart valve prosthesis is a mechanical heart valve prosthesis, particularly preferred is where the mechanical heart valve is a single leaflet disk valve or a bileaflet disk valve. Yet another preferred variation of the present embodiment is where the heart valve prosthesis is a bioprosthetic heart valve.

A further embodiment of the present invention is a method of making a tissue suture ring for use in implanting a heart valve prosthesis into a subject comprising, harvesting tissue, preferably pericardial tissue, from said subject, wherein said harvested tissue is a conical shell shaped band of tissue with a first edge conical cross section which affixes to a heart valve prosthesis, and a second edge conical cross section which affixes to a heart valve annulus. A preferred variation of the present embodiment is where the tissue is pericardial tissue. Another preferred variation of the present embodiment is where the heart valve prosthesis is a mechanical heart valve prosthesis, particularly preferred is where the mechanical heart valve is a single

leaflet disk valve or a bileaflet disk valve. Yet another preferred variation of the present embodiment is where the heart valve prosthesis is a bioprosthetic heart valve.

Terms and Definitions

As used here, the term "affixed" means to physically attach, join or fasten one object to another, such as, affixing a heart valve prosthesis to the tissue suture ring, or affixing a tissue suture ring to heart tissue. Examples of affixing include, but are not limited to suturing, gluing (as in the use of surgical or tissue adhesives), clamping with a metal or polymer wire, or staples.

As used herein, the term "backflow" refers to the direction that blood is prevented from flowing by the heart valve prosthesis.

As used herein, the term "immunocompatible donor" means a tissue donor whose tissue is sufficiently similar to that of the recipient's, such that tissue from the donor may be implanted to the recipient without tissue rejection.

As used herein, the term "outflow" refers to the direction that blood is permitted to flow through the replacement heart valve.

As used herein, the term "rendered immunocompatible" means tissues that have been treated to eliminate the risk of rejection by the recipient's immune system. Treatment can be by chemical means, for example, fixation with glutaraldehyde, or by biochemical means,

for example, using suitable agents antagonistic to saturate or otherwise render inert the antigenic sites on the tissue.

As used herein, the term "valve means" or "valving means" refers to an assembly in prosthetic heart valves which alternatively occludes and permits the flow of blood through an annulus in one direction only. For example, in mechanical heart valves typical valve means are a ball and cage assembly, a single leaflet disk valve, a bileaflet disk valve or the like. For bioprosthetic heart valves, the valve means are typically animal tissue valves, such as, bovine or porcine heart valves, or human tissue donor heart valves, assembly onto a prosthetic base.

Heart valves play a critical role in the functioning of the heart. The valves permits blood to flow in one direction, moving from a first chamber to a second chamber, while preventing the blood from backflowing from the second chamber back to the first chamber. For example, the mitral valve permits blood to flow from the left atrium into the left ventricle, while preventing blood from backflowing from the left ventricle back to the left atrium, especially when the left ventricle contracts to pump the blood through the aorta to the rest of the body. A prosthetic heart valve or heart valve prosthesis functions in place of a diseased or defective natural heart valve.

A prosthetic heart valve is made up of three primary elements, a valve means, a base with an annulus and a suture ring. The valve means is an assembly which alternatively occludes and permits the flow of blood through an annulus in one direction only. The base

corresponds to a toroidal shape. The valve means is attached to the base and blood flows through the center opening of the base, that is, the annulus of the base. The suture ring, which is sometimes referred to as the sewing ring, is a toroidal shaped structure, which is affixed to the outer circumference of the toroidal shaped annulus. Suture rings are generally made from a synthetic fiber material, such as, Dacron, Teflon, polyester, and the such. The suture ring is an element of the heart valve prosthesis that is physically affixed, most often sutured to the location in the heart where the defective natural heart valve had been removed. The prosthetic heart valve is affixed over the heart valve opening or heart valve annulus that is exposed by the removal of the defective or diseased natural heart valve.

There are two basic types of replacement heart valves, mechanical and bioprosthetic. They differ in the valve means that are utilized. Mechanical heart valves have various types of valve means, such as, a ball and cage assembly, single leaflet disk valves, or bileaflet disk valves, to control blood flow. Regardless of the valve means, mechanical valves have a base with an annulus and a suture ring or the like for affixing the valve to a location. A bioprosthetic replacement heart valve has as a valve means, animal tissue valves, or human tissue valves. Again, regardless of the origin of the tissue valves, a bioprosthetic replacement valve will have a base with an annulus and a suture ring or the like for affixing it to a location.

The present invention entails the manufacture of a tissue suture ring from autologous tissue, such as pericardium, muscle fascia, intestinal submucosa, preferably pericardium, most preferably, the pericardial

sac, affixing the tissue suture ring to a heart valve prosthesis, and the use of said tissue suture ring as a means of affixing a heart valve prosthesis, preferably a mechanical or bioprosthetic heart valve prosthesis to the operational location of the valve in the subject's heart.

The current invention can be used with any commercially available prosthetic heart valves which employs the use of a suture ring or sewing ring device for affixing the replacement valve to the heart. Prosthetic heart valves vary in the design of the valve means, that is, the means which restricts the flow of blood to one direction. Indeed, it is generally the valve means that differs from model to model and manufacturer to manufacturer. All prosthetic valves, whether mechanical or bioprosthetic, have the common feature of a base with an annulus through which the blood flows, that is required to be affixed to heart tissue at a specific location. It is to this aspect of a prosthetic heart valve that the current invention is directed. The current invention can be used to equal advantage with prosthetic mechanical heart valves having such valve means as, ball and cage, single leaflet disk and bileaflet disk, in particular, the St. Jude Valve Bileaflet valve, manufactured by St. Jude Medical, Inc., One Lillehei Plaza, St. Paul, MN 55117; the On-X Valve, manufactured by Medical Carbon Research Institute, LLC. 8200 Cameron Rd, St A-196, Austin, TX 78754; the Carbomedics Valve, manufactured by Sulzer Carbomedics, Inc. 1300 East Anderson Lane, Austin, TX 78752; and the Edwards Duromedics Valve, manufactured by Baxter-Edwards, 17221 Red Hill Ave., Irvine, CA 92614. In addition, the current invention can be used to equal advantage with bioprosthetic valves, in particular, the Carpentier-Edwards Porcine Valve, manufactured by Baxter Healthcare

Corporation, Edwards CVS Division, 17221 Red Hill Ave., Irvine, CA 92614; the Carpentier-Edwards Pericardial Valve, manufactured by Baxter Healthcare Corporation, Edwards CVS Division, 17221 Red Hill Ave., Irvine, CA 92614; and the St. Jude Toronto Stentless Porcine Valve (SPV), manufactured by St. Jude Medical, Minneapolis, MN.

Generally for a mechanical heart valve prosthesis, the suture ring assembly, which is usually part of the overall mechanical heart valve assembly is removed, and a tissue suture ring of the present invention is affixed in place of the suture ring. The combined assembly is then affixed in a standard manner known to those of ordinary skill in the art to the recipient's cardiac valve annulus, thereby replacing a defective or otherwise malfunctioning heart valve. Alternatively, the existing suture ring is not removed, instead the tissue suture ring is attached directly to the existing suture ring such that the tissue suture ring completely covers the exposed synthetic material of the pre-existing suture ring. This is particularly advantageous for the instances where the pre-existing suture ring on the replacement heart valve either cannot be removed, or cannot be removed without undue effort.

Generally, for a bioprosthetic heart valve prosthesis the pre-attached suture ring is trimmed down in size leaving just enough material for affixing the tissue suture ring. The tissue suture ring is then affixed to the outer circumference of the bioprosthetic heart valve prosthesis. The combined assembly is then affixed by a standard manner known to those of ordinary skill in the art to the location in the heart where the defective or otherwise malfunctioning heart valve had been removed. Alternatively, the existing suture ring is

not removed, instead the tissue suture ring is attached directly to the existing suture ring such that the tissue suture ring completely covers the exposed synthetic material of the pre-existing suture ring. This is particularly advantageous for the instances where the pre-existing suture ring on the replacement heart valve either cannot be removed, or cannot be removed without undue effort.

Construction of the Tissue Suture ring

A tissue suture ring can be made from pericardium, muscle fascia, intestinal submucosa, preferably pericardium, most preferably, the pericardial sac of the patient's heart. Alternatively, any of the aforementioned tissues obtained from an immunocompatible donor can also be used. Further, the tissue suture ring can be made from any of the aforementioned tissues or the like that are suitable obtained from another human or animal, for example, bovine or porcine, that has been rendered immunologically inert by chemical, biochemical or immunological techniques and methods known to those of ordinary skill in the art.

The pericardial sac is a serous membrane lining covering the outer surface of the heart. The pericardial sac is not attached to the heart, rather it is a loose fitting sac around the heart. A small amount of fluid is secreted from the sac, which lubricates heart and sac contact, and prevents the sac from adhering to the heart surface.

The pericardial tissue is harvested as follows, referring to Fig 5, a first 360° excision **10** is made approximately from 5mm to 1.5 cm from the apical tip of

the heart **11**. This first excision will define the edge of the tissue suture ring **9** that will be affixed to the heart distal from the heart valve prosthesis **16**, as shown in Figure 6. This first excision corresponds to the second edge conical cross section **1**, as depicted in Figures 9A, 9B and 9C. The placement of the first excision relative to the apical tip is based on the desired length of the tissue suture ring desired **12**, as depicted in Figure 6. The first excision is made leaving the underlining heart muscle tissue intact. A second 360° excision **13** is made near the apical tip of the detached pericardial sac, such that the perimeter length of the second 360° excision approximates the perimeter length about the base of the mechanical or bioprosthetic heart valve prosthesis that is to be implanted. The second 360° excision defines the edge of the tissue suture ring **14** that will be affixed to the heart valve prosthesis **16**, as shown in Figure 6. This second excision corresponds to said first edge conical cross section **2**, as depicted in Figure 9A, 9B and 9C. With the completion of the second excision, the tissue suture ring is completely detached from the pericardial sac, and is ready to be affixed to either a mechanical or bioprosthetic valve.

As shown in Figures 9A, 9B and 9C, the completed tissue suture is a roughly conical shell shaped band of tissue. It is understood that references to geometric shapes, such as, conical cross sections, ellipsoid, circular, trapezoidal, rectangular and the like, are only meant as approximations of the shape and appearance of the tissue suture ring. Those of ordinary skill in the art will readily understand and appreciate that the tissue suture ring does not independently

maintain the shape terms used to describe them because of the pliable nature of the tissue. However, the tissue suture ring can be oriented to roughly approximate said descriptions. When viewed from a top view, as depicted in Fig 9A, the tissue suture ring has two conical cross sections, a first edge conical cross section **2**, that is generally circular, however, can be ellipsoid which affixes to a heart valve prosthesis with a perimeter that approximates that of the prospective heart valve prosthesis to which it will be affixed, and a second edge conical cross section **1** that is generally circular, however, can be ellipsoid, which affixes to a heart valve annulus with a parameter that is marginally larger than the heart valve annulus so that said second edge conical cross section can be affixed around the outside perimeter of a heart valve annulus. The tissue suture ring when view from the cross section, as shown in Figure 9B, shows a roughly trapezoidal shape, where **1** and **2** correspond to the two sides parallel sides of a trapezoid. Depending on the size of the perimeter of the heart valve prosthesis and heart valve annulus, the cross section can vary from a trapezoidal shape to a rectangular shape, for example, where the perimeter lengths of **1** and **2** are nearly equal. rectangle like shape to a trapezoidal like shape.

The Tissue Suture ring with a Mechanical Valve

Figure 6 shows the orientation of the tissue suture ring to the mechanical valve and the direction of the flow of blood. The top of the Figure 6 is the backflow side of the valve, and the bottom of the Figure 6 is the outflow side of the valve, that is when implanted, the blood flows from the direction at the top

of the Figure to the bottom of the Figure. Still referring to Figure 6, a mechanical heart valve prosthesis **16** is prepared for implantation by removing the suture ring, if there is one present. The exposed base of the prosthesis has a surface that is typically an outwardly open annular groove **17**. The tissue suture ring is positioned relative to the mechanical heart valve **16**. The lowermost edge of the tissue suture ring **14** is positioned proximate to the backflow side of the mechanical heart valve **22**, such that when the mechanical heart valve prosthesis is implanted into the heart, the bloodflow will travel from the uppermost edge of the tissue suture ring **9** towards the lowermost edge of the tissue suture ring **14**. Referring to Fig 1B, the tissue suture ring is positioned adjacent to the outwardly open annular groove of the mechanical valve **17** by folding the lowermost edge of the tissue suture ring **14** inward and toward the backflow direction, such that a crease is formed **18** positioned at the outward flow side **19** of the open annular groove **17**. A first wire **20** is wrapped around the tissue suture ring and the annular groove proximate to the outflow side of the valve **19** affixing the tissue suture ring to the annular groove. Referring to Figure 1C, the tissue suture ring is folded back over the first wire at the crease **18**, and a second wire **21** is wrapped around the outside surface of the tissue suture ring and positioned proximate to the backflow side of the annular groove **22**. There is shown in Figure 1A the tissue suture ring affixed by the first **20** and second wires **21**, whereby the tissue suture ring is affixed to the mechanical replacement heart valve. Alternatively, the tissue suture ring may be affixed to a prosthetic heart valve where the groove **17** of the prosthetic valve is "flocked" with Dacron, or the like. "Flocking" is a

process where small particles of a material, in this example Dacron, are attached to the inner surface of the groove. The presence of the Dacron or a similar material in the groove **17** facilitates healing of the tissue suture ring to the replacement heart valve. In another alternate method for affixing the tissue suture ring to the heart valve prosthesis, as depicted in Fig **1D**, the original suture ring **11** is left on the heart valve prosthesis **16**. The outflow edge of the tissue suture ring **14** is affixed directly to the outflow side of the suture ring **17** so that the tissue suture ring covers the suture ring. The tissue suture ring provides a means of permanently connecting the mechanical heart valve to an operative position in a heart in need of a replacement valve. The combination of the mechanical replacement heart valve and tissue suture ring is implanted into the heart by suture, glue, staple or the like, where the combination is affixed to the backflow edge of the tissue suture ring **9** to the desired location in the recipient's heart.

The Tissue Suture ring with a Bioprosthetic Valve

Referring to Figure 7, a bioprosthetic heart valve prosthesis **30** is prepared by carefully trimming away portions of the suture ring **31** leaving enough of the suture ring to adequately affix the tissue suture ring to it. The valve leaflets **32** and base **33** portions of the bioprosthetic heart valve prosthesis are not modified. Referring to Figure 8, the outflow edge of the tissue suture ring **14** is positioned adjacent to the base of the bioprosthetic heart valve prosthesis **33**, such that when the bioprosthetic heart valve prosthesis is implanted into its operative position, the bloodflow will travel

from the backflow edge of the tissue suture ring **9** towards the outflow edge of the tissue suture ring **14**. Referring to Figure 1E, the outflow edge of the tissue suture ring **14** is placed over the trimmed suture ring **31** and affixed around the circumference of the base **33**. Under certain circumstances, such as, where there is adequate space, or an inability to remove the suture ring the suture ring is not trimmed and the tissue suture ring **14** is attached directly over the existing suture ring **31**. The outflow edge of tissue suture ring **14** is positioned so that it covers the covers the existing sewing ring to the leaflet base **33**.

Referring to Figures 3 and 4, the tissue suture ring is affixed to the junction of the bioprosthetic valve at the leaflet base and base of the heart valve **33** by a continuous 360° suture **34**, preferably 6-0 suture or the like, around the circumference of the base, whereby the tissue suture ring is affixed to the bioprosthetic heart valve. Alternatively, the tissue suture ring can also be affixed to a bioprosthetic heart valve base by gluing, stapling or other like means. The tissue suture ring provides a means of permanently connecting the bioprosthetic replacement heart valve in operative position in a heart in need of a replacement valve. The combination of the bioprosthetic replacement heart valve and tissue suture ring is implanted into the heart by suturing, gluing, stapling or otherwise permanently affixing the backflow edge of the tissue suture ring **19** to the recipient heart.

All commercially available heart valves, whether mechanical or bioprosthetic, incorporate into their design the use of a suture ring to affix the

replacement valve to heart tissue. The design of suture rings have been modified in an effort to improve its function and ease its implantation. However, there remains one feature that has remained constant, the materials used to make the suture rings. Suture rings are generally made from a synthetic polymer material, such as, Teflon, Dacron, polyester, polypropylene, etc. Suture rings are usually an assembly where the solid base is covered with a flexible knit polymer cloth material. This presents a coarse surface which predisposes it to thrombus early in the post operative period. Later as the healing progresses it becomes susceptible to severe pannus and fibrosis. In significantly progressive cases involving mechanical valves, these conditions can hamper the proper function of the occluder by limiting its ability to open and/or close properly. In the case of bioprosthetic valves the pannus/fibrosis usually continues from the suture ring onto the tissue leaflets commissure distorting individual leaflets and/or stiffening the leaflets of the valve to a point that they do not open or close completely. The end result is a tissue valve that is stenotic and or insufficient.

Another difficulty with the current design of suture rings is their size. Space that otherwise would be available for the heart valve is taken by the suture ring. In the case of a smaller person, the space loss to the suture ring can result in the implantation of a replacement heart valve that is smaller than optimal or preferred for the patient.

An advantage of the tissue suture ring is that it is made from pericardium. Pericardium is much more pliable and manipulative allowing for placement of a larger valve with a smaller tissue suture ring.

Pericardium is not as strong as the materials used to make synthetic suture rings, however, pericardium is sufficiently strong, durable and resilient to withstand any physiological stresses it will encounter in a clinical setting.

The current invention provides several important advantages over the existing suture rings used for both mechanical and bioprosthetic heart valve prosthesis.

A tissue suture ring has the advantage of being manufactured from tissue, which is more pliable than synthetic materials. It is therefore easier to affixed the combination of the tissue suture ring and prosthetic heart valve to any of the valve locations in the heart, for example, aortic, pulmonic, mitral, and tricuspid.

The ease in handling due to the pliability makes the replacement heart valve procedure easier and faster to accomplish. The heart valve replacement procedure is, by definition, an open heart procedure. Thus, the reduction in the length of time for the procedure has the beneficial impact of reducing morbidity and mortality of the patients undergoing the procedure.

Another advantage of the pliability of the tissue suture ring is its ability to "float" during the cardiac cycle and not be nearly as stiff and fixed as the current conventional synthetic polymer constructed suture ring designs. From a hemodynamic perspective, the floating prosthesis permits a more physiologic blood flow, and would act as a shock absorber during valve closure. The shock absorber role is instrumental in limiting damage to blood elements during left ventricular

ejection, as occurs with current mitral mechanical prostheses with standard synthetic polymer constructed suture rings. In addition the "shock absorber" feature would possibly limit the stress, trauma and long-term deleterious observed in tissue valves currently available.

Further, the tissue suture ring's flexibility and conformity has additional advantages. These characteristics makes the tissue suture readily applicable to newer implantation techniques at orthotopic valve positions utilizing alternative to suturing, such as, tissue adhesives or staples. This is turn, makes heart valve transplantation more amenable to these new technique. Implementation of these new techniques to heart valve transplantation has the immediate virtue of shortening surgical time, a benefit to patient and health care provider alike, and also, makes the heart valve transplantation procedure avenues for newer minimally invasive and "post" type surgical techniques as they developed.

The reduced bulk of a tissue suture ring over the synthetic polymer suture rings currently used, would allow the surgeon to use a larger valve, which would be beneficial to the recipient's condition. For example, the use of a larger sized valve in smaller patients would markedly reduce the incidence of prosthetic implant stenosis in this population.

Another benefit of the tissue suture rings over the existing suture rings made from synthetic materials is reduction of incidences of thrombus, pannus and fibrosis. Thrombosis is defined as an aggregate of coagulated blood containing platelets, fibrin, and

entrapped cellular elements. A thrombus is, by definition, adherent to the vascular endothelium or endomyocardium, which is distinguished from a simple blood clot, which reflects only the activation of the coagulation cascade and can form *in vitro* or *in situ* in the post mortem state. Fibrosis is the formation of fibrous tissue as a reparative or reactive process, as opposed to formation of fibrous tissue as a normal constituent of an organ or tissue. Pannus is the formation of a membrane of granulation tissue covering a normal surface. All three conditions are brought about by the presence of materials that are recognized by the body as not being part of the body. In extreme instances of these complications, additional surgery may be required to correct or negate the condition. Since the pericardial tissue suture ring is comprised of natural tissue, the incidence of the aforementioned complications are greatly reduced.

A final advantage of the pericardial valve suture ring as compared to current suture ring technology is that it will be living tissue. As such it will be much less likely to become infected. If it should become infected - treatment is much more likely to be successful when compared to a fibrotic, synthetic suture ring infection.

Although the present invention has been described with reference to preferred embodiments, workers skilled in the art will recognize that changes may be made in form and detail without departing from the spirit and scope of the invention. For example, although the specification has discussed tissue suture rings constructed from tissue from the pericardial sac of the recipient, the techniques set forth herein shall not be

limited to just this tissue. Other tissues, that may be used to provide the same advantages as tissue from pericardial sac, include muscle fascia and intestinal submucosa. In addition, tissues that have been rendered immunologically inert or tissue from immunocompatible donors can also be used advantageously to construct tissue suture rings.

WHAT IS CLAIMED:

1. A tissue suture ring which comprises a conical shell shaped band of tissue with a first edge conical cross section which affixes to a heart valve prosthesis, and a second edge conical cross section which affixes to a heart valve annulus.

2. The tissue suture ring of claim 1, wherein said tissue is pericardial tissue.

3. The tissue suture ring of claim 1, wherein said heart valve prosthesis is a mechanical heart valve prosthesis.

4. The tissue suture ring of claim 3, wherein said mechanical heart valve is a single leaflet disk valve.

5. The tissue suture ring of claim 3, wherein said mechanical heart valve is a bileaflet disk valve.

6. The tissue suture ring of claim 1, wherein said heart valve prosthesis is a bioprosthetic heart valve.

7. The tissue suture ring of claim 1, wherein said first edge conical cross section is about the circular cross section of said heart valve prosthesis.

8. The tissue suture ring of claim 1, wherein said second edge conical cross section is about the ellipsoidal cross section of said heart valve annulus.

9. A heart valve prosthesis comprising, a base having an annular outside portion and a passage allowing the flow of blood through the base, a valve means selectively movable relative to said base to open and close the passage to control the flow of blood through the passage, and a tissue suture ring which comprises a conical shell shaped band of tissue with a first edge conical cross section which affixes to a heart valve prosthesis, and a second edge conical cross section which affixes to a heart valve annulus.

10. The heart valve prosthesis of claim 9, wherein said tissue suture ring is made of pericardial tissue.

11. The heart valve prosthesis of claim 9, wherein said heart valve prosthesis is a mechanical heart valve.

12. The heart valve prosthesis of claim 11, wherein said mechanical heart valve is a single leaflet disk valve.

13. The heart valve prosthesis of claim 11, wherein said mechanical heart valve is a bileaflet disk valve.

14. The heart valve prosthesis of claim 9, wherein said heart valve prosthesis is a bioprosthetic heart valve.

15. An improved heart valve prosthesis including, a base having an annular outside portion and a passage allowing the flow of blood through the base, a valve means selectively movable relative to said base to open and close the passage to control the flow of blood through the passage, in combination with a tissue suture ring which comprises, a conical shell shaped band of tissue with a first edge conical cross section which affixes to a heart valve prosthesis, and a second edge conical cross section which affixes to a heart valve annulus.

16. The improved heart valve prosthesis of claim 15, wherein said tissue suture ring is made from pericardial tissue.

17. The improved heart valve prosthesis of claim 15, wherein said heart valve prosthesis is a mechanical heart valve prosthesis.

18. The improved heart valve prosthesis of claim 17, wherein said mechanical heart valve prosthesis is a single leaflet disk valve.

19. The improved heart valve prosthesis of claim 17, wherein said mechanical heart valve prosthesis is a bileaflet disk valve.

20. The improved heart valve prosthesis of claim 15, wherein said heart valve prosthesis is a bioprosthetic heart valve prosthesis.

21. The improved heart valve prosthesis of claim 15, wherein said bioprosthetic heart valve prosthesis is made from porcine tissue.

22. The improved heart valve prosthesis of claim 15, wherein said bioprosthetic heart valve prosthesis is made from bovine tissue.

23. A method of making a tissue suture ring for use in implanting a heart valve prosthesis into a subject comprising, harvesting pericardial tissue from said subject, wherein said harvested pericardial tissue is a conical shell shaped band of tissue with a first edge conical cross section which affixes to a heart valve prosthesis, and a second edge conical cross section which affixes to a heart valve annulus.

24. The method of claim 23, wherein said trapezoidal shaped continuous band of tissue has a first edge with a circumference about the size of the circumference of said heart valve prosthesis.

25. A method of making an improved prosthetic heart valve for implantation to a subject comprising:

(a) obtaining said prosthetic heart valve;

(b) preparing said prosthetic heart valve by modifying the suture ring from the base of said prosthetic heart valve;

(c) harvesting pericardial tissue from said subject, wherein said harvested pericardial tissue is a conical shell shaped band of tissue with a first edge conical cross section which affixes to a heart valve prosthesis, and a second edge conical cross section which affixes to a heart valve annulus; and

(d) affixing tissue suture ring to base of said prosthetic heart valve

26. The method of claim 25, wherein said prosthetic heart valve is a mechanical heart valve.

27. The method of claim 23, wherein said mechanical heart valve is a single leaflet disk valve.

28. The method of claim 26, wherein said mechanical heart valve is a bileaflet disk valve.

29. The method of claim 25, wherein said prosthetic heart valve is a bioprosthetic heart valve.

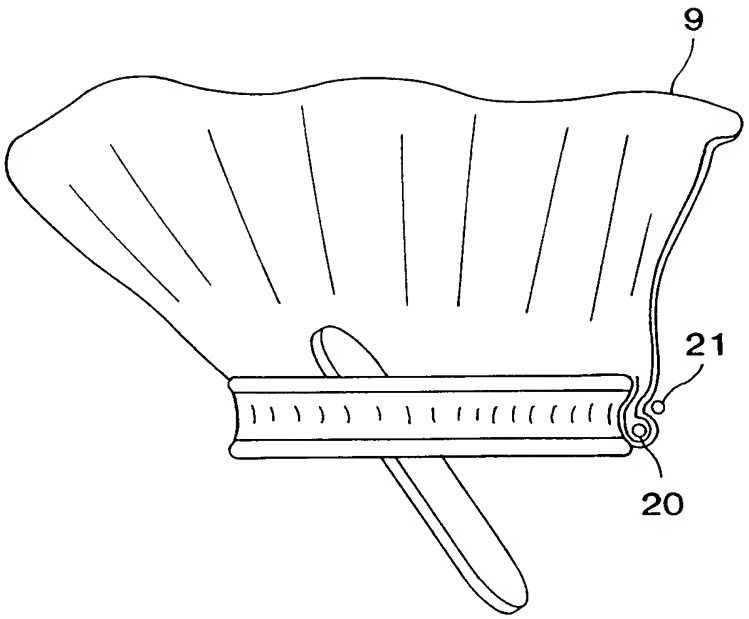

FIG. 1A

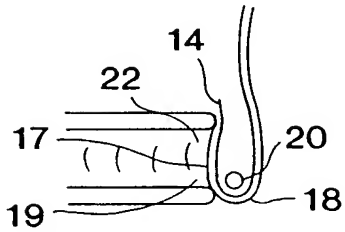

FIG. 1B

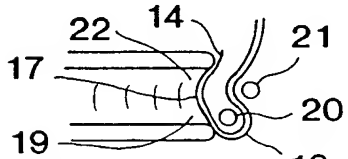

FIG. 1C

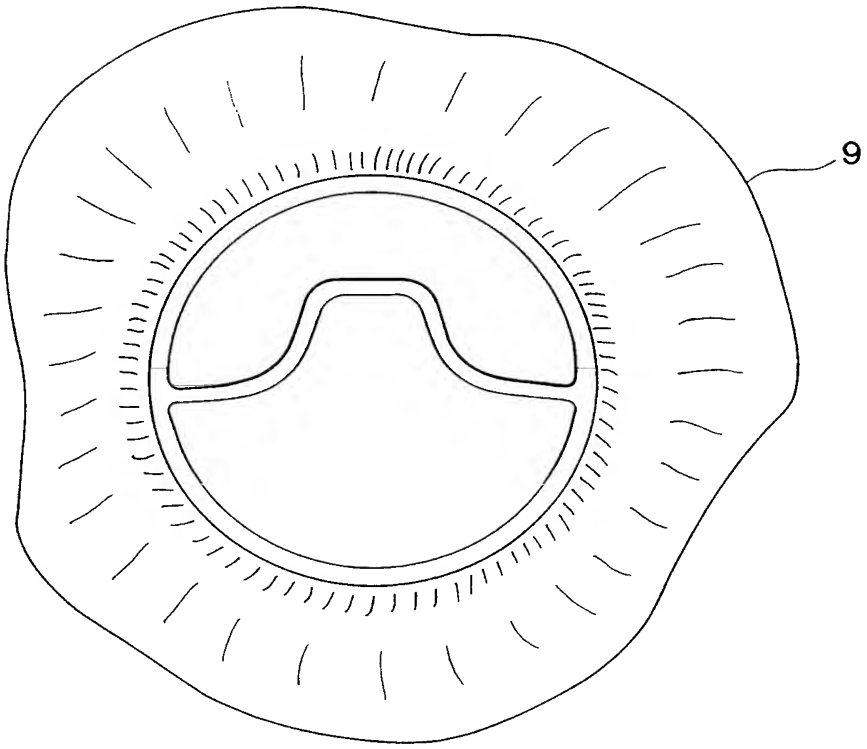

FIG. 2

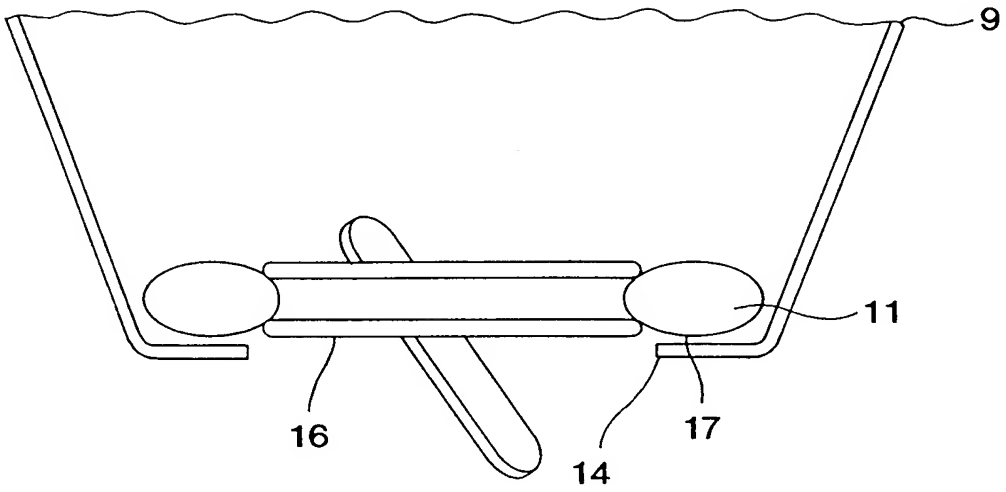

FIG. 1D

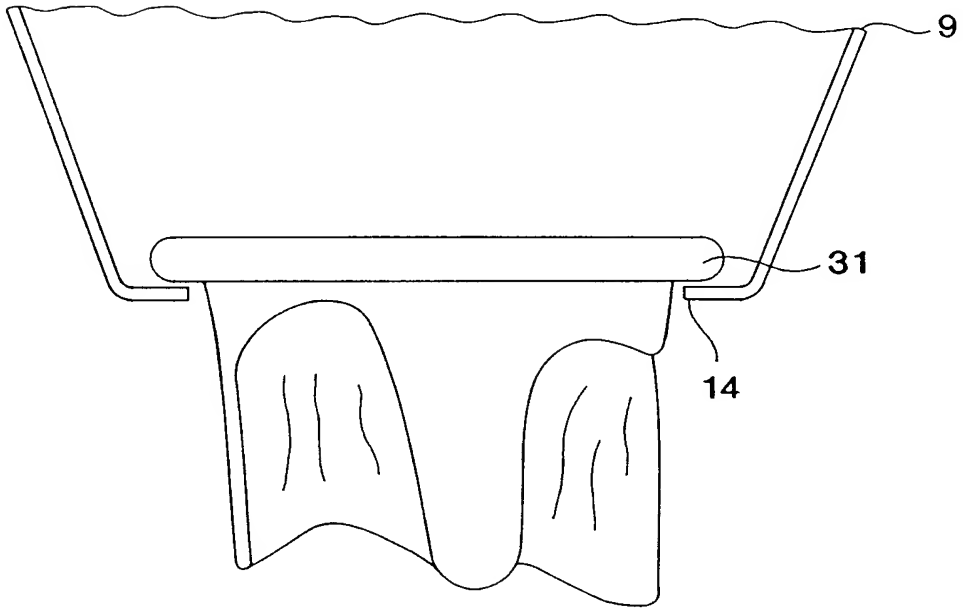

FIG. 1E

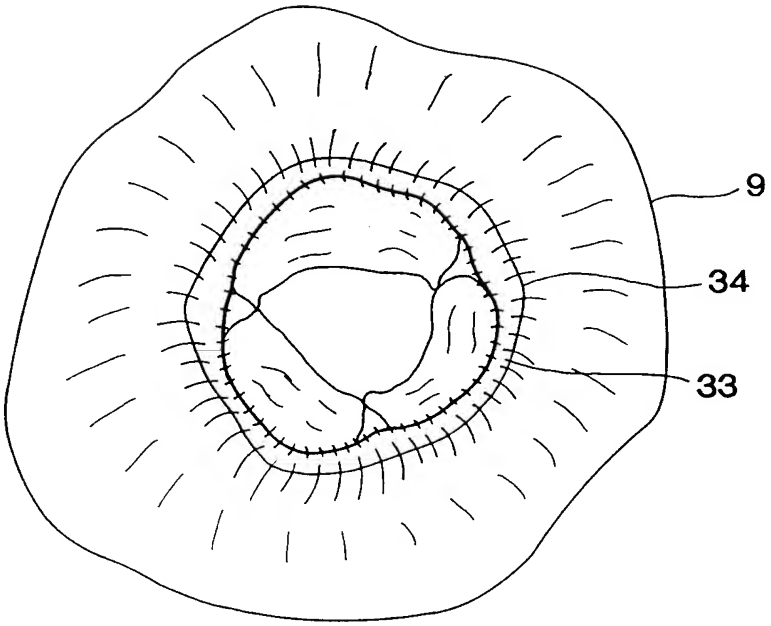

FIG. 3

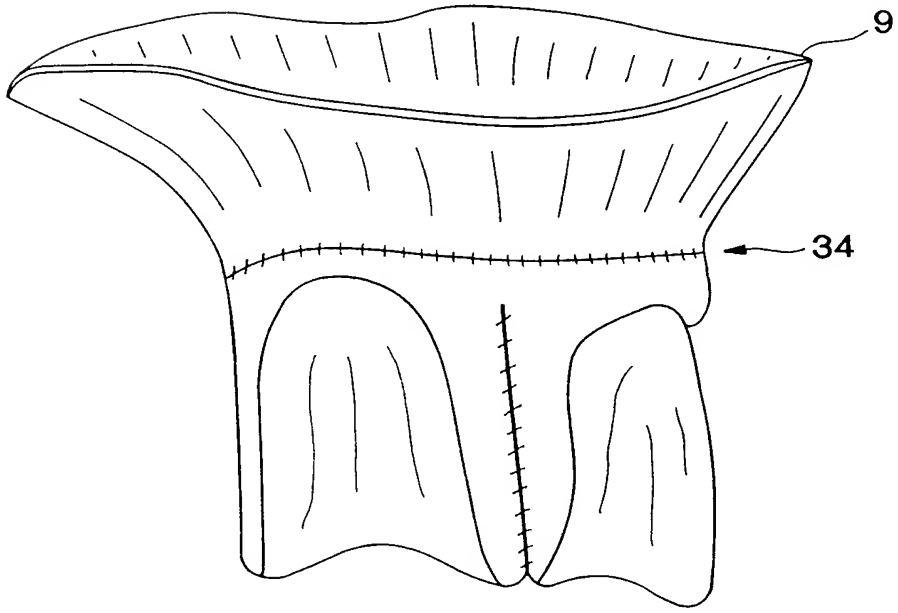

FIG. 4

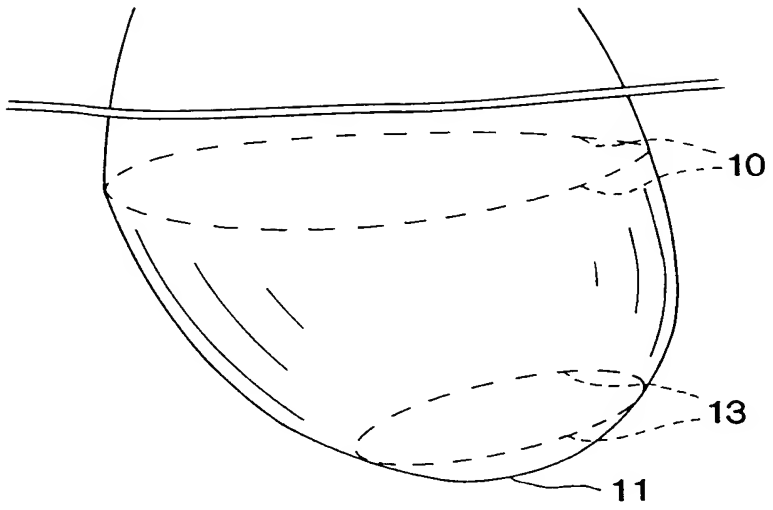

FIG. 5

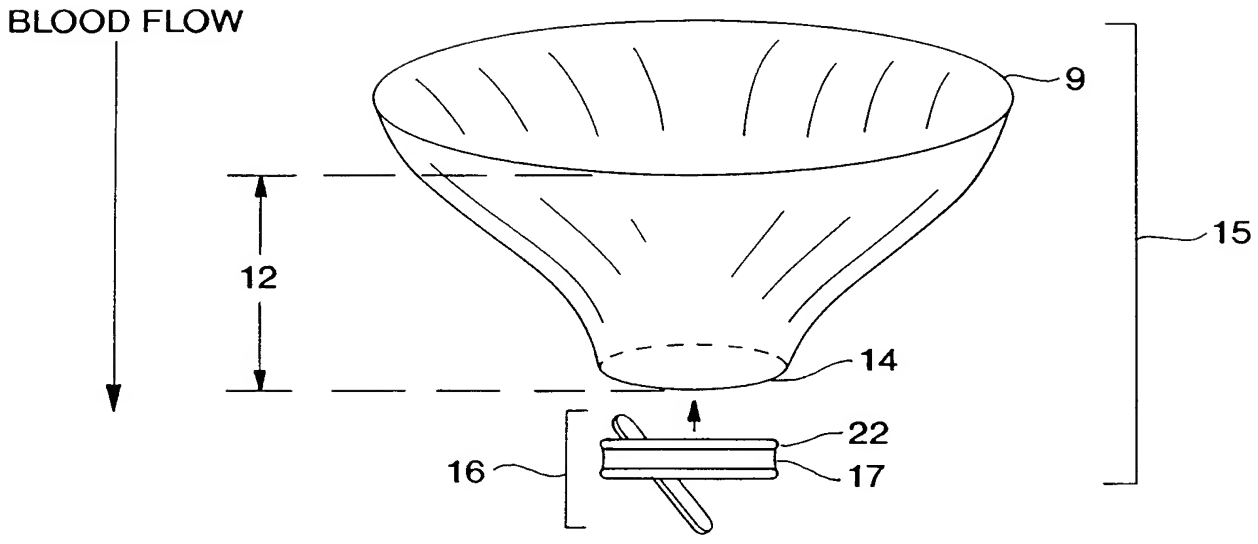

FIG. 6

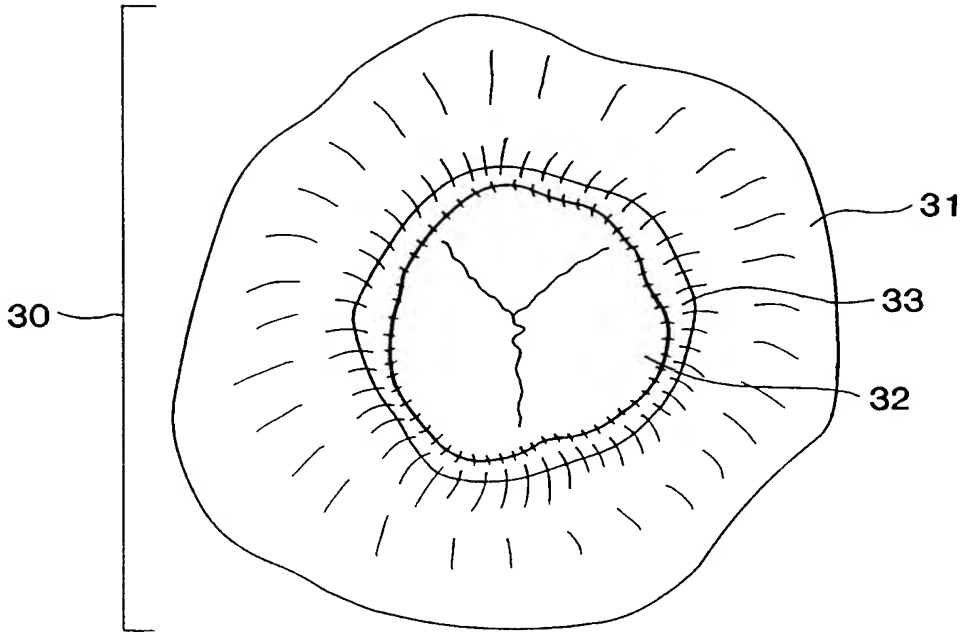

FIG. 7

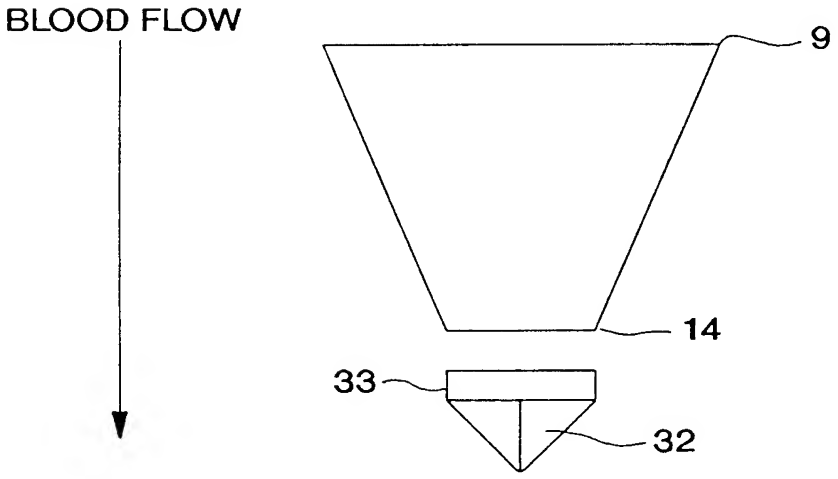

FIG. 8

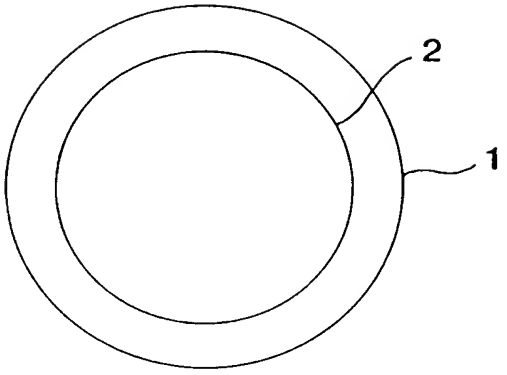

FIG. 9A

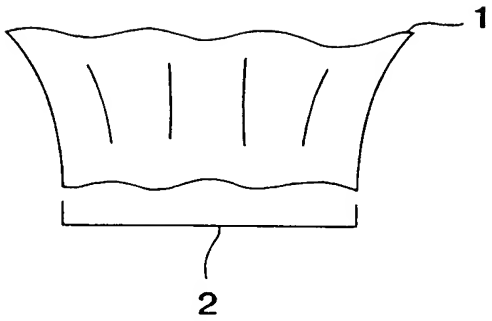

FIG. 9B

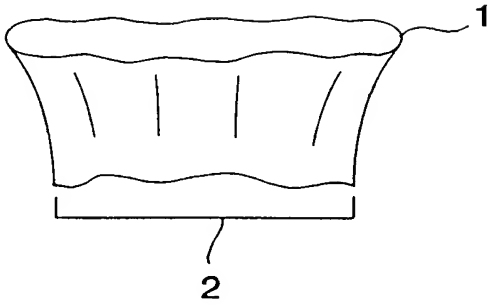

FIG. 9C

INTERNATIONAL SEARCH REPORT

Interr ıal Application No
PCT/US 00/22728

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/24

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 96 40007 A (M.O.V. PEREDO) 19 December 1996 (1996-12-19) page 9, line 33 -page 11, line 2; figures 12,13	1,2, 6-10, 14-16, 20-22
X	WO 89 00841 A (ST. JUDE MEDICAL,INC) 9 February 1989 (1989-02-09) page 3, line 3 - line 5 page 4, line 31 -page 5, line 32 page 7, line 23 - line 32; figure 4	1,3-9, 11-15, 17-20
X	WO 98 29146 A (ST JUDE MEDICAL INC.) 9 July 1998 (1998-07-09) column 4, line 19 - line 33; figures 1,3	1,2, 6-10, 14-16,20

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
19 October 2000	27/10/2000

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Wolf, C

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INTERNATIONAL SEARCH REPORT

Interr ıal Application No
PCT/US 00/22728

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

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...ormation on patent family members

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